PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2004/001311	26.03.2004	26.03.2003

International Patent Classification (IPC) or both national classification and IPC
A61K9/70

Applicant
METRIS THERAPEUTICS LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2004/001311

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 28-32 with respect to industrial applicability

because:

☒ the said international application, or the said claims Nos. 28-32 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6,8-11
	No:	Claims	1-5,7,12-32
Inventive step (IS)	Yes:	Claims	6,8,9,11
	No:	Claims	1-5,7,10,12-32
Industrial applicability (IA)	Yes:	Claims	1-27
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III. Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1

1.1 Claims 28-32 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

V. Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

For the assessment of the present claims 28-32 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2 Reference is made to the following documents:

D1 : WO 01/80937 A (METRIS THERAPEUTICS LTD ; KNOX PETER (GB)) 1 November 2001 (2001-11-01)

D2 : US 3 902 493 A (BAIER KATHLEEN GRIESHOP ET AL) 2 September 1975 (1975-09-02)

D3 : WO 01/19309 A (PROCTER &; GAMBLE) 22 March 2001 (2001-03-22)

3 INDEPENDENT CLAIMS 1,28,29,31

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1,28,29,31 is not new in the sense of Article 33(2) PCT.

3.2 Document D1 discloses (the references in parenthesis applying to this document): Drug delivery device for insertion in the vagina, rectum or nasal cavity comprising a drug such as fibrinolytic inhibitors (page 11, line 7 - page 12, line 27). An elastic lattice comprising a drug is attached to the surface of the body of the device (page 17, paragraph 1; figures 13,14). The device may comprise insertion means having a first hollow cylindrical tube and a second hollow cylindrical plunger (page 13, lines 10-16; claims 21-23).

3.3 Document D2 discloses (the references in parenthesis applying to this document): Medicated catamenial tampon comprising a foam corpus and a medicament-bearing non-woven overwrap. The overwrap is formed from a rectangular piece of material by bringing two opposite edges together forming a tube, whereby one end may be closed, yielding a tubular overwrap having the distal end closed and the proximal end open. The foam corpus is placed within the overwrap and the proximal end is fastened to form a closure. The loosely fitted overwrap fully encloses the foam corpus (column 7, line 65 - column 8, line 36). A medicament composition comprising a binding lubricant and a drug such as an antibiotic, antiseptic or anaesthetic, providing sustained release of said drug (column 11, line 10 - column 12, line 24), is applied to the overwrap.

4 INDEPENDENT CLAIM 21

4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 21 is not new in the sense of Article 33(2) PCT.

4.2 Document D1 discloses (the references in parenthesis applying to this document): Drug delivery device for insertion in the vagina, rectum or nasal cavity comprising a drug such as fibrinolytic inhibitors (page 11, line 7 - page 12, line 27). An elastic lattice comprising a drug is attached to the surface of the of the body of te device (page 17, paragraph 1; figures 13,14). The device may comprise insertion means having a first hollow cylindrical tube and a second hollow cylindrical plunger (page 13,

lines 10-16; claims 21-23).

4.3 Document D3 discloses (the references in parenthesis applying to this document): Tampon insertion device comprising a plunger (claim 1; figure 5). The device is especially adapted for insertion of a tampon into the vagina. Apparently no technical difference exists between the disclosure in D3 and the claimed device.

5 DEPENDENT CLAIMS 2-5, 7, 10, 12-20, 22-27, 30, 32
Dependent claims 2-5, 7, 10, 12-20, 22-27, 30, 32 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

VIII. Re Item VIII
Certain observations on the international application

6 The application does not meet the requirements of Article 6 PCT, because claims 19 and 20 are not clear.

6.1 Claims 19 and 20 contain references to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.